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TITLE: **Microkeratome**

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Abstract Text - ABTX (1):
A **microkeratome** is provided for use in lamellar surgery on the cornea of the eye. The **microkeratome** includes a base carrying a camshaft for rotation by a cable connected to the shaft. The base also supports a moving **blade** assembly slidably mounted on an applanator assembly, with the **blade** being thin and under tension. The moving **blade** assembly moves above and sidewardly relative to a suction ring. The moving **blade** assembly is sized to oscillate side-to-side approximately 1 **mm**. The moving **blade** assembly is driven by a connecting cable, wherein longitudinal movement of the cable produces responsive longitudinal movement of the frame and **blade** to cut a flap or disc of a desired configuration.

TITLE - TI (1):
Microkeratome

Brief Summary Text - BSTX (2):
This invention generally relates to corneal surgery, and particularly relates to a **microkeratome** for use in lamellar corneal surgery.

Brief Summary Text - BSTX (8):
As a result of certain drawbacks in other procedures, a technique enjoying increased popularity is lamellar surgery, which involves making lamellar (disk) cuts in the eye, and then removing and reshaping the disc before reattachment. The cut disk was frozen, reshaped and replaced in a procedure first developed by Dr. Barraquer known as keratomileusis. Later developments have refined this procedure and have attempted to overcome deficiencies in the technique. One recognized improvement has been the removal and retention of the uppermost layer of the cornea. This uppermost layer includes the epithelium and the Bowman's layer or membrane, which should be replaced for optimal healing of the eye. Removal of the epithelium and Bowman's membrane exposes the stroma of the cornea. The **microkeratome** removes a disc from the stroma of the desired thickness, and the surgeon then replaces the epithelium and Bowman's membrane like a cap over the lamellar cut. The preservation of the Bowman's membrane and epithelium allows the epithelial cells to reattach the cap over the stromal bed. More recent techniques, known as laser assisted in-situ keratomileusis (LASIK) uses a combination of the lamellar technique and eximer laser technique

whereby after removal of the cap, the eximer laser ablates the stromal bed to provide the desired refractive correction, then the cap is replaced as described above.

Brief Summary Text - BSTX (9):
A number of different keratomes have heretofore been developed, as shown, for example, in U.S. Pat. No. 5,591,174 to Clark et al.; U.S. Pat. No. 5,496,339 to Koepnick; U.S. Pat. No. 5,288,292 to Giraud, et al.; U.S. Pat. No. 5,133,726 to Ruiz et al.; U.S. Pat. No. 4,884,570 to Krumeich et al; and U.S. Pat. No. 4,662,370 to Hoffman et al.; and also in published International Application No. WO 93/06783. These keratomes involve a **blade** which oscillates from side to side to cut through the cornea as the **blade** moves longitudinally. The **blade** is typically driven by a cam and slot arrangement, the cam being connected to a motor drive. The **blade** is located beneath an applanator surface which flattens the arcuate surface of the eye for performing the cut, and also increases the interocular pressure within the eye, which is critical to a successful cut of the cornea. The depth of the disc cut is very precise, measured in microns, to provide proper optical correction.

Brief Summary Text - BSTX (10):
Several problems are presented by such prior art microkeratomes. One problem is the weight of the instrument which is placed on the eye. The eye is coated with a lubricating liquid (tears) and the greater the weight borne by the eye, the greater the likelihood the **microkeratome** will slip.

Brief Summary Text - BSTX (11):
Slippage of the **microkeratome** during surgery may have catastrophic results. Current microkeratomes place 5 or 6 ounces (about 150 grams) of weight offset from the eye.

Brief Summary Text - BSTX (12):
Another problem associated with the current microkeratomes is that fluid may build up beneath the applanator adversely affecting the precision of the cut. The applanator may slide along the cornea during surgery. The sliding applanator should produce a film by hydrodynamic wedge action and when stationary should produce a squeeze film when pressed against the cornea. The possibility exists for a liquid to be entrapped between the **blade** and the applanator when the liquid film collapses at its edges by

Brief Summary Text - BSTX (13):
leakage. The presence of any liquid film reduces the thickness of the cut by occupying the space between the **blade** and the applanator. Such entrapment would reduce the thickness the most at the center of the intended cut, and if thicker than the intended thickness of the disc to be cut, then a central region of the cornea will not be cut, resulting in a "button-hole".

Brief Summary Text - BSTX (17):
The present invention overcomes deficiencies in the prior art by providing an improved **microkeratome** which provides an improved cut by providing an improved suction ring, an adjustable applanator, and while allowing the surgeon to view the cut as it is being made, while measuring the interocular pressure of the eye before, during, and after the cutting process.

Brief Summary Text - BSTX (18):
Generally described, the present invention relates to the use of a **microkeratome** device, the device comprising a base assembly including a suction ring, an applanator assembly, a knife assembly configured for movement along its cutting edge axis as well as tranverse to its cutting edge axis, and a drive assembly for driving the knife assembly such that the knife moves along both axes, said drive assembly comprised of a single cored sheathed cable.

Brief Summary Text - BSTX (19):
The present invention also provides a **microkeratome** device, the device comprising a base assembly including a suction ring, an applanator assembly including an integral pressure transducer, a knife assembly, and a drive assembly for driving the knife assembly such that an eye can be cut.

Brief Summary Text - BSTX (21):
The present invention also provides a **microkeratome** device, the device comprising a base assembly including a suction ring, an applanator assembly, a knife assembly, and a drive assembly for driving the knife assembly such that an eye can be cut, the drive assembly including a seismic drive element having irregular distributions suitable to cause said knife assembly to vibrate sufficiently to cause said side-to-side cutting to occur.

Brief Summary Text - BSTX (22):
The present invention further provides a **microkeratome** device, the device comprising a base assembly including a suction ring itself including an annular cavity configured to disperse vacuum at least partially around said suction ring even when an eye is fully engaged therein, an applanator assembly, a knife assembly and a drive assembly for driving the knife assembly such that an eye can be cut.

Brief Summary Text - BSTX (23):
The present invention further provides a **microkeratome** device, the device comprising a base assembly including a suction ring, the suction ring including a first vacuum port to provide suction sufficient to cause the suction ring to be attached to an eye, the suction ring also including a second vacuum port independent of said second vacuum port routed to a vacuum gauge to detect vacuum, an applanator assembly, a knife assembly, and a drive assembly for driving the knife assembly, such that an eye can be cut.

Brief Summary Text - BSTX (24):

The present invention further provides a **microkeratome** device, the device comprising a base assembly including a suction ring, an applanator assembly hingedly removable relative to the base assembly, such that the applanator assembly may be pivoted and then removed from said base assembly while said base assembly is still in place, a knife assembly, and a drive assembly for driving the knife assembly such that an eye can be cut.

Brief Summary Text - BSTX (25):

The present invention further provides a **microkeratome** device, the device comprising a base assembly including a suction ring, an applanator assembly, a knife assembly itself comprising a knife and a knife holder holding the knife in tension, and a drive assembly for driving the knife assembly such that an eye can be cut.

Brief Summary Text - BSTX (26):

In an alternate embodiment, a **microkeratome** hereof includes a frame, an oscillator comprising an eccentric mount for rotation with a drive connector, an applanator supporting the frame, a **blade** mount carried by the frame and extending below the applanator, and a **blade** carried by the applanator for reciprocating movement caused by the oscillator. The applanator is provided with relieved areas on the bottom, eye-engaging side which may be grooves or perforations to allow the conveyance of fluid away from the **blade**, thereby reducing differences in the depth of the cut at different locations. The **microkeratome** is used with a suction ring which mounts over the eye and receives the applanator.

Brief Summary Text - BSTX (27):

In further detail, the alternate applanator is received on the suction ring and held in place thereon by cleats. The **blade** is located beneath the applanator and is oriented transverse to the longitudinal axis of the suction ring. The frame includes spaced apart feet which serve as guides and are received in tracks extending along each side of the suction ring outboard of the applanator. The feet receive **blade** clamps which extend below the applanator and secure the **blade** in tension underneath the applanator. The feet and **blade** clamps together are narrower than the tracks in the suction ring to permit oscillating movement side-to-side, typically about 1 **mm**. The frame presents a bridge connecting the guides, the bridge including a central opening. A countershaft passes through the opening and a counterweight is located on the other side. Each of the countershaft and counterweight preferably include an eccentric which are preferably substantially commonly oriented. The countershaft is coupled to a drive member such as the internal wire of a Bowden cable. The internal wire is remotely driven by a conventional motor. Typically, such motors will operate at 8,000-15,000 rpm.

Brief Summary Text - BSTX (28):

In other embodiments, the applanator will be provided with grooves or a plurality of perforations to provide relieved areas which permit fluid to be

channeled away from the **blade** and cornea. The perforations of the relieved areas will be positioned in proximity to the corneal surface of the eye to permit fluid to be drawn off, but of a size not to interfere with the cutting action of the **blade**. In the alternative, the underside of the applanator may be provided with a plurality of grooves providing a relieved area along which fluid may flow to the edges of the applanator. Furthermore, the applanator may be provided with a strain gauge for measuring the force of the eye against the applanator so that the surgeon may detect directly the intraocular pressure.

Brief Summary Text - BSTX (29):
Therefore it is an object of the present invention to provide an improved **microkeratome**.

Brief Summary Text - BSTX (30):
It is a further object of the present invention to provide an improved **microkeratome** which provides an improved cut of the eye resulting in a flap consisting of the outermost epithelium layer, the Bowman's layer, and the stroma leaving a hinge connecting the flap to the remainder of the eye.

Brief Summary Text - BSTX (31):
It is a further object of the present invention to provide an improved **microkeratome** which provides an improved suction ring.

Brief Summary Text - BSTX (32):
It is a further object of the present invention to provide an improved **microkeratome** which provides an improved suction ring which provides improved interocular pressure results.

Brief Summary Text - BSTX (33):
It is a further object of the present invention to provide an improved **microkeratome** which provides an improved suction ring which allows for more accurate interocular pressure results.

Brief Summary Text - BSTX (34):
It is a further object of the present invention to provide an improved **microkeratome** which provides an improved suction ring which allows for more accurate interocular pressure readings before, during, and after the cutting process.

Brief Summary Text - BSTX (35):
It is a further object of the present invention to provide an improved **microkeratome** which includes an applanator plate which is adjustable in height relative to the aperture of the suction ring.

Brief Summary Text - BSTX (36):
It is a further object of the present invention to provide an improved **microkeratome** which includes a hingedly removable applanator plate.

Brief Summary Text - BSTX (37):
It is a further object of the present invention to provide an improved **microkeratome** which includes a thin **blade** in tension.

Brief Summary Text - BSTX (38):
It is a further object of the present invention to provide an improved **microkeratome** which includes a moving shoe ahead of the cutting edge to provide clearance for the flap between the cutting edge and the applanator plate during the cutting process.

Brief Summary Text - BSTX (39):
It is a further object of the present invention to provide an improved **microkeratome** which includes a simplified cable drive including a single core member.

Brief Summary Text - BSTX (40):
It is a further object of the present invention to provide an improved **microkeratome** which includes a seismic drive to provide side-to-side cutting action of the **blade** along an axis parallel to its cutting edge.

Brief Summary Text - BSTX (41):
It is a further object of the present invention to provide an improved **microkeratome** which can measure pressure at the applanator plate.

Brief Summary Text - BSTX (42):
It is a further object of the present invention to provide an improved **microkeratome** which provides elastohydrodynamic entrapment relief.

Brief Summary Text - BSTX (43):
It is thus an object of the present invention to provide an improved **microkeratome** involving a minimum of moving parts, a simplified oscillating drive, and a minimum weight.

Brief Summary Text - BSTX (44):
It is another object of the present invention to provide an improved **microkeratome** which reduces film build-up beneath the applanator to provide cuts of a consistent thickness.

Brief Summary Text - BSTX (45):

It is another object of the present invention to provide an improved **microkeratome** which can be useful in reducing the loss of the "cap" consisting of the epithelium and Bowman's membrane which is to be replaced during lamellar surgery.

Brief Summary Text - BSTX (46):
It is a further object of the present invention to provide an improved **microkeratome** which allows for improved viewing of the cutting procedure as the cutting is being done.

Drawing Description Text - DRTX (2):
FIG. 1 is a bottom view of a **microkeratome** apparatus 10 in accordance with the present invention, with a remote control cable extending generally downwardly and leftwardly to the viewer.

Drawing Description Text - DRTX (4):
FIG. 3 is a top plan partial cross-sectional view of a **microkeratome** apparatus 10 in accordance with the present invention, showing a part of the applanator plate cut away to show the aperture without looking through the clear applanator.

Drawing Description Text - DRTX (6):
FIGS. 5A and 5B are front end sequential views of the device of FIG. 3, showing the side-to-side motion provided by the camshaft to the **blade** assembly.

Drawing Description Text - DRTX (12):
FIG. 10 is a side illustrative view showing the pivoting nature of the **blade** assembly 70 relative to the base assembly 20.

Drawing Description Text - DRTX (14):
FIG. 12 shows the concept of using a "bow"-like configuration to provide a cutting **blade** 75 in tension, such that a thinner cutting **blade** may used.

Drawing Description Text - DRTX (15):
FIG. 13 is a front end view of a cutting **blade** assembly 70 mounted about an applanator plate, showing the slot through which the cut eye flap may pass during the cutting process. Also shown in dotted line is an alternate seismic drive element shown in more detail in later drawings.

Drawing Description Text - DRTX (16):
FIG. 14 is a more detailed front end view of a cutting **blade** assembly 70 mounted about an applanator plate 52, except that the cutting **blade** is not shown.

Drawing Description Text - DRTX (18):
FIGS. 16 and 17 are side illustrative views showing left-to-right cutting actions of a **blade,** illustrating the use of a shoe 80 leading the cutting **blade** of FIG. 17, and the difference in the cutting action provided thereby.

Drawing Description Text - DRTX (20):
FIGS. 19 and 20 are partial front and side views, respectively, of a **blade** assembly 70 and alternate shoe configuration 80' (the one with the tangs) in engagement about an applanator plate 52.

Drawing Description Text - DRTX (21):
FIG. 21 is a top plan view of an applanator plate 52, showing a pressure transducer assembly 60 installed therein, and also showing a shoe 80 and **blade** 75 moving upwardly during the cutting process.

Drawing Description Text - DRTX (27):
FIG. 27 is a pictorial view of a second **microkeratome** apparatus 200 according to the present invention.

Drawing Description Text - DRTX (28):
FIG. 28 is a top plan view of the **microkeratome** 200 hereof, with a portion of the applanator and the securing cleat removed to show the underlying structure of the suction ring;

Drawing Description Text - DRTX (29):
FIG. 29 is a rear elevational view of the **microkeratome** of FIG. 27 showing

Drawing Description Text - DRTX (31):
FIG. 30 is a side elevational view of the **microkeratome** 200, showing the drive wire of the Bowden cable connected to the countershaft provided with the eccentric weight thereon.

Drawing Description Text - DRTX (32):
FIG. 31 is a rear end partial cross-sectional partial view of the **microkeratome** 200.

Drawing Description Text - DRTX (33):
FIG. 32 is a side view of an alternate cutting **blade** assembly 420 including two spaced-apart bushings 421 used instead of the single plastic bearing block described earlier.

Detailed Description Text - DETX (4):

In **microkeratome** 10 in accordance with the present invention generally includes a base assembly 20, with a finger grip 29 an applanator assembly 50, **blade** assembly 70, and a drive assembly 90. Other alternate mikrokeratome apparatuses will be discussed later in this application.

Detailed Description Text - DETX (5):
The **microkeratome** is useful in connection with surgery on the eye 12 shown in FIG. 18 which include a lens 13, iris 14 and comea 15. Cornea 15 is typically about 550 microns thick. In accordance with the present invention, a flap 16 about 160-175 microns in thickness is cut from the cornea, the flap including the epithelium and Bowman layer, with the flap preferably being cut to a uniform thickness but remaining connected to the eye by a hinge 17. Lifting of the flap 16 as shown in FIG. 2 exposes the stromal bed 18 for ablation by an eximer laser or other suitable techniques.

Detailed Description Text - DETX (7):
Referring generally to FIGS. 3-5B, the base assembly 20 generally includes an integral suction ring 22, and includes a subassembly referenced as a release latch assembly 30. The general function of the base assembly 20 is to provide support for various other assemblies such as the **blade** assembly 70, the applanator assembly 50, and the oscillating/linear drive assembly 90. The body also includes finger grips 29 for holding the device with the fingers.

Detailed Description Text - DETX (11):
As discussed above, one of the suction ports 26 within the annular groove 27 is connected to a conventional vacuum pump (not shown). However, one novel feature of this **microkeratome** according to the present invention is that more than one port 26 is provided, so that vacuum level may be measured directly at the fixation point rather than within a console near to the vacuum source (not shown), by attaching the other port 26 to a vacuum measuring device (not shown).

Detailed Description Text - DETX (15):
The release latches 31 are configured to engage and retain the upper surface of the applanator plate 52 proximate its forward edge, in order to releasably retain the forward edge of the applanator plate 52 in a fixed but adjustable location. Spring force to provide such retention is provided by a pair of compression springs 35 intermediate the release latches 31 and the body 21 of the base assembly 20. However, the release latches 31 may be pivoted out of the way against such spring force by moving the release trigger 34 in a direction designated as R in FIG. 4. Such trigger movement may be used to release an applanator plate 52 to gain access to the cornea or to remove and replace the **blade** as described later. It may therefore be understood that the springs 35 bias the release latches 31 downwardly onto the forward edge of the applanator plate 52.

Detailed Description Text - DETX (21):

The applanator plate 52 is preferably made of clear sapphire and is about 0.042 **inches** thick. This transparency allows one to watch the cut proceed through the clear sapphire applanator. This can be an advantage in slow cutting systems in that the cut can be stopped if it appears that damage is being done. The applanator plate 52 is substantially rigidly attached to the applanator plate mount 51.

Detailed Description Text - DETX (24):
The **Blade** Assembly

Detailed Description Text - DETX (25):
The **blade** assembly 70 generally includes a **blade holder** body 71, a **blade** 75 held within the **blade holder** 70 and a U-shaped cam-following bearing 76 configured to accept a cam member 94 of a camshaft 91 from the drive assembly as discussed elsewhere. A discussed in detail below, the camshaft 91 drives the **blade** assembly in side-to-side oscillation along the X axis (which is parallel to the cutting edge of the **blade** 75), and also pushes the **blade** generally parallel to the "Y" axis to separate the flap from the eye.

Detailed Description Text - DETX (26):
The **blade holder** body 71 includes a pair of side legs 72, a pair of **blade holder** springs 73, and a pair of mounting flanges 74, which as noted below act as "spacers". The **blade** 75 is held in tension between the mounting flanges 74 extending from the side legs 72. In one preferred embodiment, the **blade** is welded to the spacer mounting flanges, although other attachment possibilities are contemplated without departing from the spirit and scope of the present invention. The **blade** itself is preferably thin and narrow, as a thin **blade** displaces less corneal tissue in dissection. The same rigidity as a thick **blade** is achieved by placing the **blade** in tension as generally illustrated in FIG. 12 though the provision of a "bow"-shaped holder structure.

Detailed Description Text - DETX (27):
The **blade** 25 extends laterally beneath the applanator plate 52 and is preferably provided with a chisel-shaped cutting edge 25E having its lower edge leading the upper edge and thus angled downwardy and to the left as viewed in FIG. 17. This chisel-shaped orientation helps in engaging the cornea during the cutting of the flap. In the preferred embodiment hereof, the **blade** is preferably provided of stainless steel of a thickness of about 0.001 to about 0.004 **inches** thick and is about 0.035 to 0.09 **inches** wide.

Detailed Description Text - DETX (28):
The **blade** 75, being fixed within the **blade holder,** is constrained such that its cutting edge is constrained to move in a plane parallel to the primary planar surfaces of the applanator plate and at a fixed distance from the applanator. This distance defines the dissection depth (flap thickness), although this distance is not necessarily the same as the dissection depth, due to the existence of a shoe 80 leading the cutting edge as described later. The

blade assembly has a pair of **blade holder** springs 73 which engage the top surface of the applanator plate 52 proximate its side edges, keeping the **blade** assembly in upwardly biased contact with the underside of the applanator plate to provide accurate cutting.

Detailed Description Text - DETX (29):
As shown in FIGS. 5A-B, clearance between the applanator plate 52 and the **blade** assembly 70 is provided to allow the **blade** assembly 70 to be moved side-to-side when so moved by the oscillating drive assembly 90.

Detailed Description Text - DETX (31):
The shoe 80 is configured to be slidably mounted onto the applanator plate 52 such that it can be pushed in front of the **blade** cutting edge as shown in FIG. 17, to prevent the undesirable pinching effect shown in FIG. 16. The shoe is not configured to move side-to-side as does the **blade** assembly.

Detailed Description Text - DETX (33):
In a second embodiment, alternate of the shoe 80', shown in dotted line in FIG. 18 and in solid line shown in FIGS. 19 and 20, the shoe includes a pair of retention tangs 82 which allow the shoe to be retained by the **blade** assembly. Unlike the first shoe embodiment, this second shown configuration cannot be separately slid on and off the applanator plate 52 independently of the **blade** assembly 70 as shown in FIG. 10; instead the two members must be preassembled (by passing the tangs through the rectangular opening above the **blade in the blade** assembly) prior to being slid on the applanator plate 52.

Detailed Description Text - DETX (35):
Referring again generally to FIGS. 3-5B, the oscillating drive assembly 90 is mounted to the top of the applanator plate holder 51 and provides two types of motion to the **blade** assembly 70, including the **blade** 75. The first type of motion is side-to-side oscillation along the X axis , which is parallel to the cutting edge of the **blade** 75, to assist the cutting process. The second type of motion is longitudinal motion perpendicular to the cutting edge of the **blade** and generally parallel to the "Y" axis, to advance the cut along the cornea.

Detailed Description Text - DETX (37):
Referring back to FIGS. 3-5B, the bearing block 92 includes an internal elongate bore configured to accept a length of the cam shaft 91, allowing for rotational and linear movement of the camshaft 91 within the bore of the bearing block 92, which translates into the aforementioned side-to-side and longitudinal motion, respectively, of the **blade** assembly 70. The camshaft 91 rotates about an axis substantially parallel to the "Y" axis, and moves longitudinally along an axis substantially parallel to the "Y" axis when the cut is being made. This movement is caused by similar movement of the single internal strand 96 (which can be a solid wire or could be a bundle of smaller wires) within the outer sheath of the flexible control cable 95, which is driven by a remotely located electric drive motor discussed later.

Detailed Description Text - DETX (42):
A motor which can be used in conjunction with the apparatus 10 according to the present invention is shown in FIG. 30 as being used with another embodiment. Details of this motor can be referenced later, but generally described the motor is of conventional configuration for operating at 8,000-15,000 rpm, and may be manually shifted toward and away relative to the suction ring to move the **blade** longitudinally to cut the flap. It may be understood that rather than manual operation, suitable actuators may be coupled with motor to electronically control travel of the **blade** during cutting of the flap.

Detailed Description Text - DETX (44):
As noted above, the applanator plate can be raised and lowered with respect to the eye so that the applanation diameter is adjustable from 8.5-9.9 **mm**. The movement of the applanator is accomplished by the thumb-screw type arrangement described above.

Detailed Description Text - DETX (46):
In operation, the shoe 80 and the cutting **blade** assembly 70/drive assembly 90 combination are slid onto the applanator plate 52. The applanator plate assembly 50 is then attached to the base assembly 20, and locked into place by use of the release latch assembly 30. The suction ring 22 is then placed over the patient's eye and suction applied to bring the cornea up into engagement with the underside of the applanator plate 52. Adjustments to the thumbscrew 36 can then be made. The cut can then be made.

Detailed Description Text - DETX (47):
The surgeon then initiates rotation of the motor to cause the drive assembly to provide side-to-side oscillation of the **blade** assembly 70 limited by combined clearances totaling approximately one millimeter. It may be appreciated that the rotation of the drive cable 95 at approximately 8,000-15,000 rpms produces a corresponding rate of oscillation of the **blade**.

Detailed Description Text - DETX (48):
The surgeon then operates a linear actuator such as known in the art, essentially moving the motor on a plate, causing thrust to be imparted to the **blade** assembly 70, causing it to slide longitudinally along axis Y of FIG. 3. As the **blade** is positioned approximately 180 microns beneath the shoe, a flap 16 of corresponding thickness is cut in the cornea 15 as the surgeon advances the **blade**.

Detailed Description Text - DETX (49):
In the human eye, the distance of longitudinal travel will typically be about 9 **mm** to cut a flap 16 of the desired configuration, leaving hinge 17. After the flap is cut, the surgeon retracts the **blade** assembly 70. Thereafter,

the motor may be de-energized, suction discontinued to suction tube, and the suction ring removed to permit ablation of the stromal bed thus exposed by an eximer laser or other technique.

Detailed Description Text - DETX (51):
Reference is now generally made to FIGS. 27-31, for a description of a second **microkeratome** 200 embodiment.

Detailed Description Text - DETX (53):
A cutting **blade** assembly 212 includes a centrally located body 240 presenting a central opening 242 (see FIG. 31). A pair of arms 244 extend laterally and on opposite sides from the body 240 and present respective legs 250 depending downwardly therefrom. Each of the legs terminate in lowermost respective feet 252, the feet being provided with threaded holes for receiving therein clamping screws 258 (see FIG. 31). The screws 258 threadably connect **blade** mounts 260 to their respective feet 252, **blade** 216 being positioned between screws 258 on each foot 252 and held in tension therebetween. Each leg 250 also presents inwardly oriented upper applanator spring clamp 264 and relatively rigid lower applanator shelf 266 for receiving applanator 218 therebetween. Placement of the applanator 218 between upper applanator clamp 264 and shelf 266 biases the clamp 264 upwardly, whereby the applanator is secured therebetween.

Detailed Description Text - DETX (54):
The combined magnitude of the side clearances 270 will be approximately 1 **mm,** thereby defining the oscillation travel of the **blade** assembly relative to the applanator plate as described above.

Detailed Description Text - DETX (55):
Four cleats 222 hold the applanator 218 securely in position on the base 324. Base 324 includes threaded holes for receiving screws 334 therein. As may be seen in FIG. 31, feet 252 and **blade** mounts 260 extend into tracks 326 respectively but are not engaged therewith because the clamp 264 and shelf 266 couple the frame 212 to the applanator 218 without permitting such engagement.

Detailed Description Text - DETX (58):
An alternate drive configuration is also shown in FIGS. 27-31 which includes the use of an eccentric or "seismic" drive rotatably driven by a motor 224 remotely located from the suction ring. Essentially, the seismic drive concept includes the use of one or more eccentrically-weighted weights 276 which, when rotated, cause the knife assembly to move side-to-side. An applanator 218 is situated to be supported by end supports such as, 332 to thereby permit the passage of the **blade** 216 beneath the applanator 218.

Detailed Description Text - DETX (59):
An eccentric drive includes a countershaft assembly which includes a shaft

274 (see FIG. 31) extending through the bore opening of the **blade** assembly 212 and a pair of eccentric weights 276 on each end of the relatively short shaft. The countershafts are most preferably provided of a tungsten/copper alloy of about 72% tungsten and 28% copper. The shaft 274 has one end attached to the drive cable 286 and is driven thereby.

Detailed Description Text - DETX (61):
The **blade and blade holder** oscillate sidewardly with a stroke of approximately 0.9 **mm** and a rate equal to that of the eccentric masses 276 in rotation. The acceleration of the eccentric masses in the cutting plane produces a periodic force of the **blade holder** which results in reciprocation. The eccentric masses are mounted on a countershaft which can be supported in the **blade holder** by ball bearings. Axial thrust of the rotating cable flexible shaft moves the **blade** in translation. This arrangement is both simple and light-weight and free from sliding contacts.

Detailed Description Text - DETX (62):
In use, the suction ring is positioned on the eye of the patient in surrounding relationship to the eye. The frame and **blade** assembly are positioned at one longitudinal end of the applanator, which is then mounted to the suction ring. When a vacuum is applied to the suction ring via suction line 340, the applanator is drawn down on the eye (which is drawn up through aperture 336) to flatten the cornea. The motor is then actuated to turn the wire within the Bowden cable and begin rotating the countershaft and counterweights. The offset weight of the countershaft and counterweights cause the frame to move side to side on the applanator, constrained by the guides in abutment with the edge of the applanator. The offset weight of the countershaft and counterweight causes the **blade** holding frame **blade** to move from side-to-side. As the frame moves from side-to-side, the **blade** moves therewith, causing in turn a cutting action moving about 1 **mm**. The applanator remains in a fixed position over the eye, held by the cleats to the suction ring, as the frame carrying the **blade** is advanced longitudinally therealong by pushing on the wire. The frame is advanced or pulled rearwardly in the tracks by movement of the wire relative to the sheath, the wire being moved either manually by the surgeon pushing the remotely positioned motor or through the use of a conventional actuator such as a micro controller coupled to a stepper motor for incrementally advancing the motor coupled to the internal wire.

Detailed Description Text - DETX (76):
The keratome apparatuses according to the present were conceived to fill the need for a **microkeratome** dedicated to the dissection of a corneal flap required for ophthalmic surgical procedures. Consultation with surgeons led to the following list of preferences:

Detailed Description Text - DETX (77):
1) The instrument should be small, and without excessive volume and mass. In currently available **microkeratome** devices, the weight of a heavy motor extending many centimeters from the center of the fixation device applies a

torque to the eye/keratome interface which tends to compromise fixation.

Detailed Description Text - DETX (82):
In order to reduce weight and overfusing mass, under the invention the drive motor have been removed from the **microkeratome** and placed in a console. A single drive cable provides driving force with a flexible drive member made of a single strand or braided steel wire.

Detailed Description Text - DETX (84):
Therefore it may be seen that the present invention provides an improved **microkeratome** for use in lamellar corneal surgery.

Claims Text - CLTX (1):
1. A **microkeratome** device for use with an eye, said device comprising;

Claims Text - CLTX (6):
2. A **microkeratome** device, for use with an eye said device comprising;

Claims Text - CLTX (12):
3. A **microkeratome** device for use in conjunction with a remote vacuum source, said device comprising;

Claims Text - CLTX (17):
4. A **microkeratome** device for use in applanating and cutting an applanated eye, said device comprising;

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TITLE: Corneal surgical apparatus

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Detailed Description Text - DETX (20):

Upon completion of the fixing of the apparatus, the cutting unit 2 is tilted using the screw 50 to adjust the height of the tip (blade edge) of the blade 20 with respect to the suction ring. 31. If the cutting unit 2 is inclined in an upwardly oriented manner, the height of the blade edge becomes large, and a small flap is formed as compared to a state in which the cutting unit 2 is horizontal. On the other hand, if the cutting unit 2 is inclined in a downwardly oriented manner, the height of the blade edge becomes small, and a large flap is formed as compared to the state in which the cutting unit 2 is horizontal. Accordingly, it suffices that in a case where the corneal curvature is large and thus the height of the cornea projecting from the suction ring 31 (the opening 31b) becomes large, the cutting unit 2 is inclined in the upwardly oriented manner, whereas in a case where the corneal curvature is small and thus the height of the cornea projecting from the suction ring 31 becomes small, the cutting unit 2 is inclined in the downwardly oriented manner. Similarly, it suffices that in a case where the flap diameter is to be small, the cutting unit 2 is inclined in the upwardly oriented manner, whereas if the flap diameter is to be large, the cutting unit 2 is inclined in the downwardly oriented manner. In the apparatus of this embodiment, if the height of the blade edge is changed by 0.1 **mm** in a case where the corneal curvature is 7.8 **mm**, the flap diameter is changed by 0.3 **mm**.

0.012"

0.31"

.004"